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53

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,876	05/10/2001	Carol Gebert	CG-3	5158

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,876

Applicant(s)

GEBERT ET AL.

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is recited as being dependent on claim 5, which is indefinite. As such, the remaining dependent claims are indefinite, as the scope of the claim is not determined. As can best be determined by the examiner, claim 5 was intended to depend from claim 4, and has been treated as such in an examination on the merits of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al. Leary discloses prior art flow cytometer systems that analyzes cells or particles that are stained with a dye or other labeling compound, excited with a light source and analyzed by photodetectors that convert fluorescence into electrical signals, and then sort the labeled particles according to an electrical charge (column 1, lines 47-65). Leary teaches that such methods are used to detect minimal residual diseases that have a very low cell count (column 2, lines 10-18). Leary does not disclose a means for withdrawing blood from a patient, nor does he disclose a means for maintaining particles in a viable state. However, conventional flow cytometers inherently comprise a means for obtaining fluid for processing. Davidner discloses a blood treatment system with a means for withdrawing blood from a patient via venous cannula 101 and pump 102 that provides a withdrawal force to get blood from the patient (column 4, lines 15-25). The device further provides a UV irradiator 104 that modifies the particles in the tubing system and a hemoconcentrator 106 with a filtration membrane that serves a reservoir means for maintaining the particles in a viable state before returning the treated blood to the patient via tubing 107, which removes the treated particles from the

Art Unit: 3762

hemoconcentrator/reservoir. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the cell labeling and sorting device disclosed by Leary with the cell treating, maintaining, and return device disclosed by Davidner in order to detect, separate, and treat toxic cells, returning good blood to the patient, as taught by Davidner.

6. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, further in view of US 6,197,593 to Deka et al. The modified Leary device discloses the apparatus as claimed with the exception of using a red-excited dye. Deka discloses the use of a membrane-permanent red-excited dye to distinguish between different types of blood cells, including specific nucleic acid components. Therefore, it would have been obvious to one of ordinary skill in the art to use a membrane-permanent red-excited dye in the cell sorting mechanism disclosed by Leary in order to discriminate between nucleic acid components, as taught by Deka.

7. Claims 15, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, further in view of US 6,119,031 to Crowley. The modified Leary device discloses the apparatus as claimed with the exception of an implantable analysis system. Crowley discloses an implantable spectrophotometer with a light source and a plurality of light detectors therein. The light detectors convert optical signals into electrical signals to characterize the tissue in question (column 2, lines 44-60). Therefore, it would have been obvious to one of ordinary skill in the art to make the flow cytometer and pump disclosed by Leary

Art Unit: 3762

and Davidner of a sufficient size to be implanted in the body in order to minimize the need for large, expensive, and technically challenging analyzers, as taught by Crowley. Furthermore, a change in size is generally recognized as being within the capabilities of someone with ordinary skill in the art.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, in view of US 6,119,031 to Crowley, further in view of US 6,142,146 to Abrams et al. The modified Leary device discloses the apparatus as claimed with the exception of providing a means to produce electrical power when the pump is actuated. Abrams discloses a device for providing inhalants to a patient with a pump 80 that receives a signal to begin pumping, thereby causing the pump circuit 80 to generate electricity (column 7, lines 7-20). Therefore, it would have been obvious to one of ordinary skill in the art to combine the modified cell sorting system taught by Leary with the electricity-generating pump taught by Abrams in order to cut down on large energy requirements for driving the electrical apparatus, as taught by Abrams.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 3,910,256 Clark et al
 - i. Automated blood analysis system
- b. US 5,341,805 Stavridi et al

Art Unit: 3762

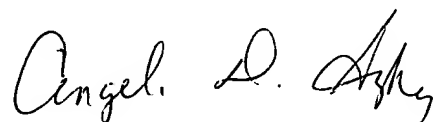
- ii. Glucose fluorescence monitor that may be used in a flow line
- c. US 6,228,652 Rodriguez et al
- iii. Method and apparatus for analyzing cells in whole blood

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd
October 29, 2002



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700